K111007

510(k) Summary

JUN - 8 2011

In accordance with 21 CFR Part 807.92, this summary is submitted by:

Midwestern Reprocessing Center
3995 Fashion Square Blvd. Suite 11
Saginaw, MI 48603
Registration Number: Not yet applied

Date Prepared:

1. Contact Person

Scott Senner
Consultant
Phone: (205) 314-3920
Fax: (205) 314-3959
Email: scott.senner@hygia.net

2. Name of Device

Classification Name:	Oximeter, Tissue Saturation
Common Name:	Oximeter, Cerebral/Somatic
Trade or Proprietary Name:	Midwestern Reprocessing Center (MRC) Reprocessed Cerebral-Somatic Oximetry Sensors

3. Predicate Device

Corresponding Somanetics oximetry sensors legally marketed under various 510(k) premarket notifications:

Somanetics Corp.	K082327
Somanetics Corp.	K080769
Somanetics Corp.	K051274
Somanetics Corp.	K001842
Somanetics Corp.	K971628
Somanetics Corp.	K960614

4. Device Description

Midwestern Reprocessing Center (MRC) Reprocessed Cerebral-Somatic Oximetry Sensors (CSS) are optical devices which use dual-wavelength light to determine a patient's current regional oxygen saturation level. Once a sensor has been applied to the patient, a light source in the sensor sends red and near-infrared light through the skin surface and photodiodes measure the reflected light. This signal is sent back to a monitor which calculates the patient's trending oxygenation levels.

5. Device Intended Use

Midwestern Reprocessing Center (MRC) Reprocessed CSS are intended to be used in the same manner as the predicate devices. They are designed to be applied to the forehead and other appropriate portions of the body to measure regional oxygenation saturation during surgery or other applications related to the use of anesthesia. The devices are intended to be used in hospitals.

6. Technological Characteristics

The Midwestern Reprocessing Center (MRC) CSS are identical to the original OEM devices in reference to the technological characteristics.

7. Performance Data

Functional testing, cleaning validation, and biocompatibility data demonstrates that the reprocessed oximetry sensors perform as intended, and are safe and effective.

8. Conclusion

Based on the assessment of functional testing, cleaning validation, and biocompatibility data, Midwestern Reprocessing Center (MRC) concludes that the Midwestern Reprocessing Center (MRC) Reprocessed CSS are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 8 2011

Midwest Reprocessing Center LLC
% Hygia Health Services, Inc.
Mr. Scott Senner
434 Industrial Lane
Birmingham, Alabama 35211

Re: K111007
Trade/Device Name: Midwest Reprocessing Center (MRC) Reprocessed Cerebral-Somatic Oximetry Sensor (CSS)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NMD
Dated: April 07, 2011
Received: April 11, 2011

Dear Mr. Senner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

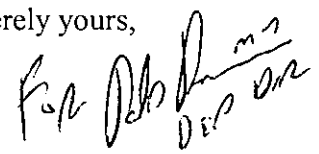
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if Known): K 111007

Device Name: Midwest Reprocessing Center (MRC) Reprocessed Cerebral-Somatic Oximetry Sensor (CSS)

Indications For Use:

The Midwest Reprocessing Center (MRC) Reprocessed Cerebral-Somatic Oximetry Sensors are indicated for use when continuous noninvasive trending of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor is required.

Prescription Use __Yes___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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